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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/486,823 03/03/00 SHIMADA

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EXAMINER

SPIVACK, P

ART UNIT

PAPER NUMBER

1614

DATE MAILED:

09/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/486,823

Applicant
Shimada et al.

Examiner
Phyllis G. Spivack

Group Art Unit
1614



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-5 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-5 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1614

A Preliminary Amendment filed March 3, 2000, Paper No. 3, is acknowledged. Claims 1-4 are under consideration.

An Information Disclosure Statement filed June 5, 2000, Paper No. 4, is further acknowledged and has been reviewed. The required Form PTO-1449 is not present with the Information Disclosure Statement filed August 11, 2000.

Submitted a "substantially equivalent" form

Claims 4 and 5 are objected to under 37 CFR 1.75© as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claim 5 provides for the use of a xanthine derivative, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 5 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

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Claims 1-5 are vague and indefinite with respect to the recitation within the definitions of R⁵ and Z "substituted or unsubstituted aryl" and "substituted or unsubstituted heterocyclic group". The metes and bound of "substituted" cannot be precisely determined. Applicants should recite those substituents contemplated within the definitions.

The parenthetical subject matter in claim 1 renders the claim indefinite. It is unclear whether or not a claim limitation is intended.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for exhibiting the pharmacological activity of inhibition of neurodegeneration following the application of four test compounds, as disclosed in Table 2, page 12, does not reasonably provide enablement for compounds of formula I wherein any heterocyclic group is attached. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to prepare and to practice the invention commensurate in scope with these claims. In consideration of the plethora of diverse functionalities represented within "heterocyclic group" and the absence of support in the specification for the breadth of the claims, one skilled in the art would be unable to prepare and practice the invention without undue experimentation.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:-

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Schweiss et al., U.S. Patent No. 3,641,010.

Schweiss teaches pharmaceutical compositions of instant formula I for use as cerebral stimulants. It is well established in the pharmacology art that the central nervous system stimulant methylphenidate is used in the treatment of attention deficit hyperactivity disorder which Applicants list among the neurodegenerative disorders encompassed in the claims. See the top of page 13 of the specification.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al., U.S. Patent No. 5,484,920.

Suzuki teaches pharmaceutical compositions of instant formula I for use in the treatment of Parkinson's disease, a neurodegenerative disorder.

No claim is allowed.

Lau et al., Journal of Neurochemistry, is cited to show the state of the art with respect to the activity of adenosine analogues as endogenous neuroprotective agents.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number (703) 308-4703.

September 8, 2000

Phyllis Spivack

**PHYLLIS SPIVACK
PRIMARY EXAMINER**